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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,245	02/18/2004	Jaime Romero	OSMO-1001	5228

7590 11/30/2006  
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EXAMINER

AHMED, HASAN SYED

ART UNIT PAPER NUMBER

1615

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/782,245	ROMERO, JAIME	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 51 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-50, 52-54, and 56-67 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                      |                                                                    |
|--------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>11/24/06</u>                             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date ____.                                                          | 6) <input type="checkbox"/> Other: ____.                           |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, 48-50 and 52, drawn to a composition comprising a stabilizing agent, classified in class 424, subclass 451.
- II. Claims 23-25, drawn to a composition lacking a stabilizing agent, classified in class 424, subclass 451.
- III. Claims 26-45, drawn to a composition consisting of a core and a semipermeable coating, and comprising a stabilizing agent, classified in class 424, subclass 451.
- IV. Claims 46 and 47, drawn to a composition consisting of a core and a semipermeable coating, and lacking a stabilizing agent, classified in class 424, subclass 451.
- V. Claims 53 and 54, drawn to a process of making a composition comprising a stabilizing agent, classified in class 424, subclass 457.
- VI. Claims 56-58, drawn to a process of making a composition lacking a stabilizing agent, classified in class 424, subclass 457.
- VII. Claim 59, drawn to a method of analyzing a composition, classified in class 424, subclass 451.
- VIII. Claim 60, drawn to a method of treating arthritis in a mammal comprising glucosamine, classified in class 514, subclass 825.

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- IX. Claims 61-63, drawn to a method of maintaining healthy bones and joints in a mammal comprising glucosamine, classified in class 514, subclass 825.
- X. Claim 64, drawn to a method of treating arthritis in a mammal comprising chondroitin, classified in class 514, subclass 825.
- XI. Claims 65-67, drawn to a method of maintaining healthy bones and joints in a mammal comprising chondroitin, classified in class 514, subclass 825.

\* \* \* \* \*

Claim 1 links inventions I and VIII-XI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 1. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claim will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant

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application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

\* \* \* \* \*

The inventions are distinct, each from the other for the following reasons:

***Groups I-XI***

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the composition of Group I claims a stabilizing agent not required by Group II. The subcombination has separate utility such as use in a depot formulation.

Inventions I and III are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the composition of Group III claims a core and a semipermeable coating not required by Group I. The subcombination has separate utility such as use in a depot formulation.

Inventions I and IV are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the composition of Group IV claims a core and a

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semipermeable coating not required by Group I. The subcombination has separate utility such as use in a depot formulation.

Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as spray granulation.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group I is drawn to a composition comprising a stabilizing agent, while group VI is drawn to a process of making a composition lacking a stabilizing agent.

Inventions I and VII are unrelated. In the instant case, Group I is drawn to a composition comprising a stabilizing agent, while group VII is drawn to a method of analyzing a composition.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process

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for using the product as claimed can be practiced with another materially different product, such as a transdermal formulation.

Inventions I and IX are related as product and process of use. In the instant case, the process for using the product as claimed can be practiced with another materially different product, such as a transdermal formulation.

Inventions I and X are related as product and process of use. In the instant case, the process for using the product as claimed can be practiced with another materially different product, such as a transdermal formulation.

Inventions I and XI are related as product and process of use. In the instant case, the process for using the product as claimed can be practiced with another materially different product, such as a transdermal formulation.

#### ***Groups II-XI***

Inventions II and III are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the composition of Group III claims a core and a semipermeable coating not required by Group II. The subcombination has separate utility such as use in a depot formulation.

Inventions II and IV are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the composition of Group IV claims a core and a semipermeable coating not required by Group II. The subcombination has separate utility such as use in a depot formulation.

Inventions II and V are unrelated. In the instant case, Group II is drawn to a composition lacking a stabilizing agent, while group V is drawn to a process of making a composition comprising a stabilizing agent.

Inventions II and VI are related as process of making and product made. In the instant case the product as claimed can be made by another and materially different process, such as spray granulation.

Inventions II and VII are unrelated. In the instant case, Group II is drawn to a composition comprising a stabilizing agent, while group VII is drawn to a method of analyzing a composition.

Inventions II and VIII are unrelated. In the instant case, Group II is drawn to a composition lacking a stabilizing agent, while group VIII is drawn to a method of treating arthritis in a mammal using a composition comprising a stabilizing agent.

Inventions II and IX are unrelated. In the instant case, Group II is drawn to a composition lacking a stabilizing agent, while group XI is drawn to a method of maintaining healthy bones and joints in a mammal using a composition comprising a stabilizing agent.

Inventions II and X are unrelated. In the instant case, Group II is drawn to a composition lacking a stabilizing agent, while group X is drawn to a method of treating arthritis in a mammal using a composition comprising a stabilizing agent.

Inventions II and XI are unrelated. In the instant case, Group II is drawn to a composition lacking a stabilizing agent, while group XI is drawn to a method of



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maintaining healthy bones and joints in a mammal using a composition comprising a stabilizing agent.

***Groups III-XI***

Inventions III and IV are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the composition of Group III claims a stabilizing agent not required by Group IV. The subcombination has separate utility such as use in a depot formulation.

Inventions III and V are unrelated. In the instant case, Group III is drawn to a composition consisting of a core and a semipermeable coating, while group V is drawn to a drawn to a process of making a composition lacking a core/coating construction.

Inventions III and VI are unrelated. In the instant case, Group III is drawn to a composition consisting of a core and a semipermeable coating, while group VI is drawn to a drawn to a process of making a composition lacking a core/coating construction.

Inventions III and VII are unrelated. In the instant case, Group III is drawn to a composition consisting of a core and a semipermeable coating, while group VII is drawn to a method of analyzing a composition.

Inventions III and VIII are unrelated. In the instant case, Group III is drawn to a composition consisting of a core and a semipermeable coating, while group VIII is drawn to a method of treating arthritis in a mammal using a composition lacking a core/coating construction.

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Inventions III and IX are unrelated. In the instant case, Group III is drawn to a composition consisting of a core and a semipermeable coating, while group IX is drawn to a method of maintaining healthy bones and joints in a mammal using a composition lacking a core/coating construction.

Inventions III and X are unrelated. In the instant case, Group III is drawn to a composition consisting of a core and a semipermeable coating, while group X is drawn to a method of treating arthritis in a mammal using a composition lacking a core/coating construction.

Inventions III and XI are unrelated. In the instant case, Group III is drawn to a composition consisting of a core and a semipermeable coating, while group XI is drawn to a method of maintaining healthy bones and joints in a mammal using a composition lacking a core/coating construction.

#### ***Groups IV-XI***

Inventions IV and V are unrelated. In the instant case, Group IV is drawn to a composition consisting of a core and a semipermeable coating, while group V is drawn to a drawn to a process of making a composition lacking a core/coating construction.

Inventions IV and VI are unrelated. In the instant case, Group IV is drawn to a composition consisting of a core and a semipermeable coating, while group VI is drawn to a drawn to a process of making a composition lacking a core/coating construction.

Inventions IV and VII are unrelated. In the instant case, Group IV is drawn to a composition consisting of a core and a semipermeable coating, while group VII is drawn to a method of analyzing a composition.

Inventions IV and VIII are unrelated. In the instant case, Group IV is drawn to a composition consisting of a core and a semipermeable coating, while group VIII is drawn to a method of treating arthritis in a mammal using a composition lacking a core/coating construction.

Inventions IV and IX are unrelated. In the instant case, Group IV is drawn to a composition consisting of a core and a semipermeable coating, while group IX is drawn to a method of maintaining healthy bones and joints in a mammal using a composition lacking a core/coating construction.

Inventions IV and X are unrelated. In the instant case, Group IV is drawn to a composition consisting of a core and a semipermeable coating, while group X is drawn to a method of treating arthritis in a mammal using a composition lacking a core/coating construction.

Inventions IV and XI are unrelated. In the instant case, Group IV is drawn to a composition consisting of a core and a semipermeable coating, while group XI is drawn to a method of maintaining healthy bones and joints in a mammal using a composition lacking a core/coating construction.

#### ***Groups V-XI***

Inventions V and VI are unrelated. In the instant case, Group V is drawn to a process of making a composition comprising a stabilizing agent, while group VI is drawn to a process of making a composition lacking a stabilizing agent.

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Inventions V and VII are unrelated. In the instant case, Group V is drawn to a process of making a composition, while group VII is drawn to a method of analyzing a composition.

Inventions V and VIII are unrelated. In the instant case, Group V is drawn to a process of making a composition, while group VIII is drawn to a method of treating arthritis in a mammal.

Inventions V and IX are unrelated. In the instant case, Group V is drawn to a process of making a composition, while group IX is drawn to a method of maintaining healthy bones and joints in a mammal.

Inventions V and X are unrelated. In the instant case, Group V is drawn to a process of making a composition, while group X is drawn to a method of treating arthritis in a mammal.

Inventions V and XI are unrelated. In the instant case, Group V is drawn to a process of making a composition, while group XI is drawn to a method of maintaining healthy bones and joints in a mammal.

### ***Groups VI-XI***

Inventions VI and VII are unrelated. In the instant case, Group VI is drawn to a process of making a composition, while group VII is drawn to a method of analyzing a composition.

Inventions VI and VIII are unrelated. In the instant case, Group VI is drawn to a process of making a composition, while group VIII is drawn to a method of treating arthritis in a mammal.

Inventions VI and IX are unrelated. In the instant case, Group VI is drawn to a process of making a composition, while group IX is drawn to a method of maintaining healthy bones and joints in a mammal.

Inventions VI and X are unrelated. In the instant case, Group VI is drawn to a process of making a composition, while group X is drawn to a method of treating arthritis in a mammal.

Inventions VI and XI are unrelated. In the instant case, Group VI is drawn to a process of making a composition, while group XI is drawn to a method of maintaining healthy bones and joints in a mammal.

#### ***Groups VII-XI***

Inventions VII and VIII are unrelated. In the instant case, Group VII is drawn to a method of analyzing a composition, while group VIII is drawn to a method of treating arthritis in a mammal.

Inventions VII and IX are unrelated. In the instant case, Group VII is drawn to a method of analyzing a composition, while group IX is drawn to a method of maintaining healthy bones and joints in a mammal.

Inventions VII and X are unrelated. In the instant case, Group VII is drawn to a method of analyzing a composition, while group X is drawn to a method of treating arthritis in a mammal.

Inventions VII and XI are unrelated. In the instant case, Group VII is drawn to a method of analyzing a composition, while group XI is drawn to a method of maintaining healthy bones and joints in a mammal.

***Groups VIII-XI***

Inventions VIII and IX are unrelated. In the instant case, Group VIII is drawn to a method of treating arthritis in a mammal, while group IX is drawn to a method of maintaining healthy bones and joints in a mammal.

Inventions VIII and X are unrelated. In the instant case, Group VIII is drawn to a method of treating arthritis in a mammal using glucosamine, while group X is drawn to a method of treating arthritis in a mammal using chondroitin.

Inventions VIII and XI are unrelated. In the instant case, Group VIII is drawn to a method of treating arthritis in a mammal, while group XI is drawn to a method of maintaining healthy bones and joints in a mammal.

***Groups IX-XI***

Inventions IX and X are unrelated. In the instant case, Group IX is drawn to a method of maintaining healthy bones and joints in a mammal, while group X is drawn to a method of treating arthritis in a mammal.

Inventions IX and XI are unrelated. In the instant case, Group IX is drawn to a method of maintaining healthy bones and joints in a mammal using glucosamine, while group XI is drawn to a method of maintaining healthy bones and joints in a mammal using chondroitin.

***Groups X-XI***

Inventions X and XI are unrelated. In the instant case, Group X is drawn to a method of treating arthritis in a mammal, while group X is drawn to method of maintaining healthy bones and joints in a mammal.

\* \* \* \* \*

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

\* \* \* \* \*

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

\* \* \* \* \*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

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§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

\* \* \* \* \*

This application contains claims directed to the following patentably distinct species:

Group I:

- Species I - Election of Nutritional Supplement Group:
  - a. Nutritional supplement group of Claim 5
  - b. Nutritional supplement group of Claim 6
- Species II – Dissolution Profile:
  - a. Dissolution profile of Claim 48
  - b. Dissolution profile of Claim 50
- Species III – Dissolution Profile:
  - a. Dissolution profile of Claim 49
  - b. Dissolution profile of Claim 52

Group III:

- Election of Nutritional Supplement Group:
  - a. Nutritional supplement group of Claim 30
  - b. Nutritional supplement group of Claim 31

\* \* \* \* \*



Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 and 26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

\* \* \* \* \*

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

\* \* \* \* \*

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

★

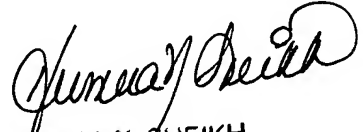
### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
HUMERA N. SHEIKH  
PRIMARY EXAMINER  
TC-1600